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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,135	05/31/2001	Brandon James Yoe	50623.00168	1923

7590 02/06/2003

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EXAMINER

NGUYEN, TU C

ART UNIT	PAPER NUMBER
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3749

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,135

Applicant(s)

YOE ET AL.

Examiner

Tu C. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7 and 9-45 is/are pending in the application.
- 4a) Of the above claim(s) 4 nad 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-32,37-39 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-3, 5-7 and 9-45 in Paper No. 11 is acknowledged. Claims 4 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected claims, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Response to Applicant's Election

Examiner contacted Applicant's representative, Mr. Cameron Kerrigan, to discuss the claim language as reading on the elected species of Figure 1. The discussion include the limitations of (a) the "a plurality of indentations" recited in claims 33-36, (b) the "indenting a surface" recited in claim 40, and (c) the "indentations" recited in claim 45. Mr. Kerrigan agreed that they are not readable on the elected species of Figure 1 and authorized Examiner to withdraw them from consideration.

Claims 1-3, 5-7, 9-32, 37-39, and 41-44 considered to be readable on the elected species of Figure 1 and have been examined as follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

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(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-3, 5-7, 9-16, 21-32, 37-39, are rejected under 35 U.S.C. 102(e) as being anticipated by Turnlund et al (Publication No. US2001/0001806A1). Turnlund et al discloses in Figures 3 and 5 a conventional stent-graft delivery system (28) comprising an expandable radioisotope stent-graft (23) with a deformable, tubular stent (20) mounted onto the balloon (31) at the distal portion of the stent-graft delivery system (28). Turnlund teaches preferably radioisotopes include alpha, beta, or low energy gamma emitters with the endovascular radiation dose ranges from about 1 Gy to about 600 Gy. The stent-graft (23) constructed to deliver a dose of endovascular radiation upon the selected region (21) and the anatomy of the stent (25) include the central region (38), the proximal portion (41), and the distal portion (40) and Turnlund further teaches that stent-graft (23) having an uniform radioactivity longitudinally therealong will not emit at a uniform rate of radiation near the proximal and distal portions (41, 40), as compared to the center region (38) of the stent graft, thereby, Turnlund appreciates the radiation dosages should not be as high at the proximal and distal portions (41, 40). Figure 6 illustrates a graphical chart illustrating the Dose to Tissue vs. Distance From the Surface of Stent (paragraphs [0031], [0036], [0037], [0045], [0048], [049], [0051], [0052], [0056-0061]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-20, 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turnlund et al (Publication No. US2001/0001806A1). Turnlund et al discloses in Figures 3 and 5 a conventional stent-graft delivery system (28) comprising elements set forth in these claims including the stent graft (23) having a coating of biological growth factor to form a template in which cells may adhere. As regards to forming of coating in dipping or spraying recited in these claims is an obvious matter of design choice which provides no unusual, unobvious, or unexpected results and is therefore deemed to fall within the purview of ordinary engineering technique.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Crocket et al of U.S. Patent No. 5,782,742 discloses in Figures 1 a radiation delivery catheter (10) is provided with an inflatable multilayered balloon (18) mounted at the distal end (16), the balloon having a continuous annular radiation delivery layer thereon. Crocket teaches that the balloon catheter embodying features such as carrying an implantable stent but does not teach that the stent containing gradients of therapeutic agent such as radiation dose.

Fischell et al of U.S. Patent No. 5,059,166 discloses in Figure 1 a cross sectional area (10) of two turns of a helical coil spring stent that has been fabricated from a pure metal or alloy which has been irradiated so that it has become radioactive, i.e., it is radioisotope in form of alpha,

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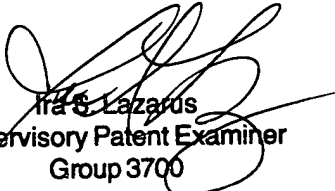
beta, or gamma emitter. Fischell lacks the teaching of the stent having a central region with radioactivity gradients while the both outer ends, the proximal end and a distal end, are transitioning the to a non-therapeutic radioactivity level.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tu C. Nguyen whose telephone number is 703-305-0537. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on 703-308-1935. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Tu C. Nguyen
January 31, 2003


Ira S. Lazarus
Supervisory Patent Examiner
Group 3700